UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,531	06/21/2007	Rodrigo Franco	AM102286	9924

25291 7590 10/28/2008

WYETH
PATENT LAW GROUP
5 GIRALDA FARMS
MADISON, NJ 07940

EXAMINER	
DANG, IAN D	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
10/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,531	FRANCO ET AL.	
	Examiner	Art Unit	
	IAN DANG	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-13,17,18,20,40,41,43,46 and 47* is/are pending in the application.

4a) Of the above claim(s) *11-13,17,20,40,41,43,46 and 47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/17/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-6, 8-10, and 18 in the reply filed on 09/08/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-13, 17, 20, 40-41, 43, 46, and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 09/08/2008.

Claims 1-6, 8-10, and 18 are under examination.

Claim Objections

Claims 2, 4, 6, 8 and 18 are objected to because of the following informalities:

Claim 2 is objected to because the recitation of “essentially consists of” is unclear. The recitation of “consists essentially of” would overcome objection.

Claim 6 is objected to because claim 6 fails to further limit claim 5. Since both claims are open claim language, they are interpreted as “comprising”.

Appropriate correction is required.

Specification

The disclosure is objected to because of the following informalities:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Appropriate correction is required.

Information disclosure statement

The information disclosure statement filed 09/17/2008 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The references that include GenBank® Accession Numbers NM 006922, GenBank® Accession Numbers AF225986, GenBank® Accession Numbers NM 013119, GenBank® Accession Numbers NM 018732, GenBank® Accession Numbers NM 013199 have not been considered by the Examiner because these references do not have any date disclosed on the PTO-1449. Please submit a courtesy copy of the references and a new PTO-1449.

Claim Rejections - 35 USC § 101-non-statutory subject matter

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 10 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

Claim 10 reads on the presence of the nucleic acid inside a cell or an animal that relates to gene therapy. Claim 10 reads on a product of nature in that the claimed host cell is not

"isolated". In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty,* 447 U.S. 303, 206 USPQ 193 (1980).

Claim Rejections - 35 USC § 112, Second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is indefinite because the recitation of "polypeptide activity in a cell" is indefinite. It is not clear as to what activities in a cell are encompassed in the claim. For instance, the polypeptide activity may be the sodium current, the closing and opening of the channel, or the signal transduction caused by the $mNa_v1.3$ α subunit, or some other, undefined activity.

Claim Rejections - 35 USC § 112 (Written Description)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 18 is drawn to a method for modulating a mNav1.3 α subunit polypeptide activity in a cell comprising: providing a sodium channel comprising a $mNa_v1.3$ α subunit polypeptide; and contacting the channel with an amount of a $mNa_v1.3$ α subunit polypeptide modulator effective to modulate an activity of the $mNa_v1.3$ α polypeptide.

Although Applicant discloses the biological activity of the modulator, Applicant has not provided any information regarding the identifying structural characteristics of the modulator that can be used to modulate an activity of the $mNa_v1.3$ α polypeptide. The specification and the claim fail to disclose any identifying structural characteristics of the modulator that can be used to modulate an activity of the $mNa_v1.3$ α polypeptide in the claimed method.

Therefore, Applicant has not satisfied the requirement for written description because the modulator in the claimed method encompasses a genus of modulators whose identifying structural characteristic are not described. The specification does not provide any representative examples of this genus of modulators and does not provide any teachings sufficient to one of skill in the art to identify the numerous modulators that can be used to modulate an activity of the $mNa_v1.3\alpha$ polypeptide encompassed by the claims. Thus, Applicants have not provided any identifying structural characteristics or properties of the instant m modulators such that one of skill would be able to predictably identify the encompassed modulators that can be used to modulate an activity of the $mNa_v1.3\alpha$ polypeptide of the instant claims.

Based on Applicants' disclosure and knowledge within the art, those of skill in the art would conclude that Applicants would not have been in possession of the claimed genus of modulators that can be used to modulate an activity of the $mNa_v1.3\alpha$ polypeptide. Thus, applicant was not in possession of the claimed genus and the written description requirement is not satisfied.

Claim Rejections - 35 USC § 101/112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" – A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention.

"Substantial" – A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" – Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the Applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

See also the MPEP at § 2107-2107.02.

Claims 1-6, 8-10, and 18 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation.

Specifically, claim 1 is drawn to an isolated sodium channel type III α subunit ($mNa_v1.3$ α subunit) polypeptide, wherein the polypeptide comprises the amino acid sequence of SEQ ID NO:2, and claim 4 is drawn to an isolated $mNa_v1.3$ α subunit nucleic acid molecule that encodes the polypeptide.

The specification of the instant application discloses that the novel $mNa_v1.3$ α subunit subunit coding sequence (SEQ ID NO: 1), which is approximately 5940 nucleotides in length, encodes a protein which is approximately 1980 amino acid residues in length. The gene encoding this novel subunit is expressed in the brain. $Na_v1.3$ channels are expressed, e.g., in brain, heart, and skeletal muscle. An $Na_v1.3$ channel can be expressed at low or high levels in a given tissue. Some $Na_v1.3$ channels expressed in neurons are upregulated following neuronal injury (Waxman, SG, et al. Brain Res. 8886:5-14, 2000; Kim, CH, et al. Mol. Brain Res. 95:153-161, 2001) (page 10, lines 7-14).

However, the instant specification does not teach any functional characteristics of the $mNa_v1.3$ α subunit polypeptide of SEQ ID NO:2 or the nucleic acid of SEQ ID NO:1 encoding the polypeptide. The specification does not disclose the polypeptides in the context of a cell or organism or any methods or working examples that indicate the polypeptides of the instant invention is involved in any activities or diseases states. Since significant further research would be required of the skilled artisan to determine how the polypeptide encoded by the claimed nucleic acid molecule is involved in any activity, the asserted utilities are not substantial. Since the utility is not presented in mature form and significant further research is required, the utility is not substantial. The specification asserts the following as patentable utilities for the claimed putative polypeptide of SEQ ID NO:2 and the nucleic acid of SEQ ID NO:1 encoding the polypeptide:

1) to screen test compounds for drug discovery (page 40, line 11 to page 52, line 25)

2) to provide predictive medicine including diagnostic assays, prognostic assays, monitoring clinical trials, and pharmacogenetics (page 52, line 26, to page 59 line 14)

3) to provide a method of treatment including therapeutic and prophylactic (page 64, line 14 to page 65, line 25)

Each of these shall be addressed in turn.

1) to screen compounds for drug discovery. This asserted utility is not specific or substantial. Such assays can be performed with any polypeptide or polynucleotide. Nothing is disclosed about how the polynucleotide or polypeptide is affected by the compounds. Additionally, the specification discloses nothing specific or substantial for the molecular targets that can be identified/selected/validated by this method. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

2) to provide predictive medicine. This asserted utility is not specific or substantial. Such assays can be performed with any polynucleotide or polypeptide. Although the specification discloses that the gene of the encoding this novel subunit is expressed in the brain (page 10, line 10), the specification also discloses nothing about the normal levels of expression of the polypeptide or a specific target receptor. The specification does not disclose any disorders associated with the $mNa_v1.3$ α subunit polypeptide of SEQ ID NO:2 or the nucleic acid of SEQ ID NO:1 encoding the polypeptide. Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

3) to provide a method of treatment. This asserted utility is not specific or substantial.

The disclosed method of treatment can be performed with any polypeptides. Further, the specification does not disclose a specific disease or condition that can be treated with the $mNa_v1.3$ α subunit polypeptide of SEQ ID NO:2 or a disease associated with the $mNa_v1.3$ α subunit polypeptide of SEQ ID NO:2. Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

Claims 1-6, 8-10, and 18 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, credible utility, asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

No claim is allowed.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
October 21, 2008

/Robert Landsman/
Primary Examiner, Art Unit 1647